UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL CO, LIMITED, et al. Plaintiff, v. ZYDUS PHARMACEUTICALS USA INC., et al. Defendant.	Civil Action No. 10-1723 (JAP) **OPINION**

PISANO, District Judge.

Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, Takeda Pharmaceuticals America, Inc., and Ethypharm, S.A. (collectively, "Takeda" or "Plaintiffs") bring this Hatch-Waxman patent infringement action against defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (together, "Defendants") claiming infringement of three patents alleged to cover Takeda's Prevacid SoluTab product ("SoluTab"): U.S. Patent Nos. 6,328,994 (the " '994 patent"), 7,431,942 the " '942 patent"), and 5,464,632 (the " '632 patent").

Presently before the Court is the parties' request for claim construction. The Court held a *Markman* hearing on May 26, 2011. This Opinion addresses the proper construction of the disputed claim terms.

I. The Technology and Patents-In-Suit

The three patents at issue claim a pharmaceutical dosage form known as an orally disintegrating tablet ("ODT"). An ODT is a tablet formulation that disintegrates in the mouth rapidly in the presence of saliva without the need for water. An ODT provides advantages to children, the elderly or anyone who may have difficulty swallowing conventional tablets and capsules.

The '994 and '942 patents, both entitled "orally disintegrable tablets", concern ODT formulations containing fine granules of enteric-coated acid-labile drug. The '632 patent, entitled "rapidly disintegrating multiparticular tablet", claims an ODT with excipient mixture of a swelling agent and disintegrating agent that allows it to disintegrate rapidly in the mouth in less than 60 seconds. Upon disintegration, the active substance is present in the form of coated microcrystals or coated or uncoated microgranules.

II. Standards for Claim Construction

In order to prevail in a patent infringement suit, a plaintiff must establish that the patent claim "covers the alleged infringer's product or process." *Markman v. Westview Instrs., Inc.*, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). Consequently, the first step in an infringement analysis involves determining the meaning and the scope of the claims of the patent. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 988 (Fed. Cir. 1995). Claim construction is a matter of law, *Markman v. Westview Instrs., Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) *aff'd* 517 U.S. 370 (1996), therefore, it is "[t]he duty of the trial judge . . . to determine the meaning of the claims at issue." *Exxon Chem. Patents, Inc. v. Lubrizoil Corp.*, 64 F.3d 1553, 1555 (Fed. Cir. 1995).

In *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005), the Federal Circuit emphasized that "[i]t is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." 415 F.3d 1312 (internal quotations omitted) (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576 (Fed. Cir. 1996) ("we look to the words of the claims themselves . . . to define the scope of the patented invention"); *Markman*, 52 F.3d at 980 ("The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims."). Generally, the words of a claim are given their "ordinary and customary meaning," which is defined as "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1312-13 (citations omitted). In this regard, the Federal Circuit has noted that

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning and usage in the field. The inventor's words that are used to describe the invention--the inventor's lexicography--must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decisionmaking process by reviewing the same resources as would that person, viz., the patent specification and the prosecution history.

Id. (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed.Cir.1998)).

In the process of determining the meaning of a claim as understood by a person of ordinary skill in the art, a court may look to various sources from which the proper meaning may be discerned. These sources include "the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the art." *Id.* at 1314.

While a court is permitted to turn to extrinsic evidence, such evidence is generally of less significance and less value in the claim construction process. *Id.* at 1317. Extrinsic evidence would include evidence that is outside the patent and prosecution history, and may include expert testimony, dictionaries and treatises. *Id.* The Federal Circuit has noted that caution must be exercised in the use of extrinsic evidence, as this type of evidence may suffer from inherent flaws affecting its reliability in the claim construction analysis. *Id.* at 1319 ("We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms."). While "extrinsic evidence may be useful to the court, . . . it is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence."

III. The Disputed Claim Terms

The parties have identified a number of disputed claim terms in each patent. The Court will address each of these in turn.

1. The '994 Patent

a. *"fine granules having an average particle diameter of 400 µm or less"*

This phrase appears in Claim 1 of the '994 patent. Plaintiffs contend that this phrase means "fine granules up to and including the enteric coating layer having an average particle diameter of 400 µm (±10%) or less." D.I. 94 at Revised Ex. A at 1. Defendants argue that the Court should construe the phrase as meaning the following:

> "fine granules having an average particle diameter of precisely 400 µm or less" wherein the term "average particle diameter" references the "median diameter" value of the fine granules (as set forth in the specification of U.S. Patent No. 6,328,994 col. 5, ll. 43-46, when measured within the tablet (as set forth in claim 1).

Id. at 1. Defendants to not dispute that the coating of the composition is measured when determining average particle diameter.

The parties dispute as to this claim term is two-fold. The first dispute centers on the phrase "average particle diameter" within the disputed claim term. Plaintiffs argue that no construction is necessary and the plain and ordinary meaning of the phrase should apply. Defendants, on the other hand, argue that "average particle diameter" is limited to the "median diameter" value of the fine granules when measured within the tablet. However, the portion of the specification relied upon by the Defendants does not limit "average particle diameter" to just the median diameter. Indeed, the specification states that "[a]verage particle diameter means volume based distribution median diameter (median diameter: 50% particle diameter from cumulative distribution), *unless otherwise specified*." '994 patent, col. 5, lines 43-45 (emphasis added). Thus, to extent that Defendants seek a construction of the phrase "average particle diameter", the Court sees no reason to limit it as Defendants contend. The Court finds no ambiguity with phrase and its ordinary and customary meaning would be clear to one skilled in the art. Therefore, no construction is necessary.

The parties' remaining dispute centers on whether the claim limitation of "400μm or less" should be read as 400μm (± 10%) or as "precisely" 400 μm or less. As Plaintiffs point out, the specification is clear that "fine granules having a particle diameter of 400 μm or less" is not precise. First, the specifications states:

> In the present invention, "fine granules having an average particle diameter of 400 μm or less, which fine granules comprise a composition coated by an enteric coating layer, said composition having 10 weight % or more of an acid-labile physiologically active substance" have an average particle diameter of about 400 μm or less, in order that roughness is not felt in the mouth.

'994 patent, col. 5, lines 57-63. It further states elsewhere: "[E]specially when used in an orally disintegrable tablet, the average particle diameter of the included granules must be about 400 µm or less, preferably about 350 µm." *Id.*, col. 2, lines18-21. Thus, the specification correlates "average particle diameter of 400 µm or less" with "an average particle diameter of *about* 400 µm or less."

The specification in the '994 patent notes that a measurement of "average particle diameter" can be obtained utilizing a laser diffraction particle distribution method, for example, "a method using Raser Diffraction Analyzer, type: HEROS RODOS [trade name; manufactured by Sympatec (Germany)]. '994 patent, col. 5, lines 46-47 (brackets in original). This is, in fact, the instrument used in performing such an analysis with respect to the examples in the specification. *See* '994 patent, col. 19, lines 32-37. According to Plaintiff's expert, Dr. Byrn, a deviation of 10% for measurements by laser diffraction particle distribution is universally accepted. *See* Byrn Decl. ¶¶ 28-30. In support of his conclusion, Dr. Byrn points to the U.S. Pharmacopeia ("USP") standard, which has been accepted and used by others skilled in the art. See *id.*, Ex. 6.

Defendants dispute the applicability of 10% deviation figure. Defendants, however, do not necessarily dispute in substance the authorities relied upon by Dr. Byrn, but rather argue that the authorities relied upon by Dr. Byrn postdate the relevant patent application. Based upon an academic publication from 2002, Defendants argue that the figure during the relevant time period was not 10%, but rather was less than 3%. See Def. Brf. at 10 (citing R. Xu, *Paricle Characterization: Light Scattering Methods* (2002) at 166 ("… a modern commercial instrument should easily achieve a relative standard deviation less than 3% of the median value in repeat measurement…"). However, the Court is not persuaded by such

reference, as Defendants provide no basis for the Court to conclude that the state of the technology is such that its accuracy actually became worse over time.

For the reasons above, the Court shall adopt Plaintiff's construction, and define "fine granules having an average particle diameter of 400 μm or less" to mean "fine granules up to and including the enteric coating layer having an average particle diameter of 400 μm (±10%) or less."

b. *"said composition having 10 weight % or more of an acid-labile physiologically active substance that is lansoprazole"*

This phrase appears in Claim 1 of the '994 patent. Plaintiff argue that this disputed phrase should be construed as "said composition up to but not including the enteric coating layer having 10 weight % or more of an acid-labile physiologically active substance that is lansoprazole". D.I. 94 at Revised Ex. A at 2. Defendants, on the other hand, contend that this claim limitation does not require construction and should be considered to have its plain meaning. If, however, the Court determines that construction is appropriate, Defendants argue that this phrase should be construed as: "said composition is an enteric coated granule having 10 weight % or more of an acid-labile physiologically active substance that is lansoprazole". *Id.*

The basic difference in the parties' construction centers on whether the "composition" includes the enteric coating layer (as Defendants contend) or excludes the enteric coating layer (as Plaintiffs contend). The Court finds that the claim language itself dictates the Plaintiffs' construction. Claim 1 of the '994 patent reads as follows:

> An orally disintegrable tablet which comprises (i) fine granules having an average particle diameter of 400 μm or less, which fine granules comprise a composition coated by an enteric coating layer comprising a first component

> which is an enteric coating agent and a second component which is a sustained-release agent, said composition having 10 weight % or more of an acid-labile physiologically active substrate that is lansoprazole and (ii) an additive wherein said tablet having a hardness strength of about 1 to about 20 kg, is orally disintegrable.

As the "composition" is "coated by an enteric coating layer", the "composition" must necessarily be exclusive of the enteric coating layer. Further, contrary to the arguments of Defendants, the Court finds in the record no "clear and unmistakable disclaimer" of such a reading by the patentee. *See Ecolab, Inc. v. FMC Corp.*, 569 F.3d 1335, 1342 (Fed. Cir. 2009) (disclaimer may be found "only if the allegedly disclaiming statements constitute a clear and unmistakable surrender of subject matter …. Even if an isolated statement appears to disclaim subject matter, the prosecution history as a whole may demonstrate that the patentee committed no clear and unmistakable disclaimer.) (internal quotations and citations omitted).

Consequently, the Court construes "said composition having 10 weight % or more of an acid-labile physiologically active substance that is lansoprazole" consistent with Plaintiff's proposed construction: "said composition up to but not including the enteric coating layer having 10 weight % or more of an acid-labile physiologically active substance that is lansoprazole".

c. *"wherein the average particle diameter of the fine granule is 300 to 400 µm"*

This phrase appears in claim 2 of the '994 patent. Plaintiffs proffer the following proposed construction: "wherein the average particle diameter of the fine granule is 300 to 400 µm (±10%)". D.I. 94 at Revised Ex. A at 4. Defendants argue that the Court should construe the phrase as meaning the following:

> "fine granules having an average particle diameter of precisely 400 µm or less" wherein the term "average particle diameter" references the "median diameter" value of the fine granules (as set forth in the specification of U.S. Patent No. 6,328,994 col. 5, ll. 43-46, when measured within the tablet (as set forth in claim 1).

Id.

For the reasons above in section III(1)(a) of this Opinion (construing "fine granules having an average particle diameter of 400 µm or less"), the Court adopts Plaintiffs' proposed construction, and shall construe "wherein the average particle diameter of the fine granule is 300 to 400 µm" as meaning "wherein the average particle diameter of the fine granule is 300 to 400 µm (±10%)". The phrase "average particle diameter" shall have its plain and ordinary meaning as understood by one skilled in the art.

2. The '942 Patent

a. *"fine granules having an average particle diameter of 300 to 400 µm"*

This phrase appears in claim 1 of the '942 patent. Plaintiffs contend the limitation should be construed as meaning "fine granules up to and including the enteric coating layer and mannitol coating layer outside the enteric coating laying having an average particle diameter of 300 to 400 µm (±10%)". D.I. 94 at Revised Ex. A at 6. Defendants argue that the phrase should be construed as follows:

> "fine granules having an average particle diameter of precisely 300 to 400 µm or less" wherein the term "average particle diameter" references the "median diameter" value of the fine granules (as set forth in the specification at U.S. Patent No. 6,328,994 col. 5, ll. 43-46), when measured within the tablet (as set forth in claim 1)

Id.

Defendants do not dispute that the fine granules comprise a composition coated by an enteric coating layer and a coating layer comprising mannitol outside the enteric coating

layer, and do not dispute that such coatings are measured when determining average particle diameter. Consequently, for the reasons above in section III(1)(a) of this Opinion (construing "fine granules having an average particle diameter of 400 µm or less"), the Court adopts Plaintiff's proposed construction, and shall construe "fine granules having an average particle diameter of 300 to 400 µm" as meaning "fine granules up to and including the enteric coating layer and mannitol coating layer outside the enteric coating laying having an average particle diameter of 300 to 400 µm (±10%)". The phrase "average particle diameter" shall have its plain and ordinary meaning as understood by one skilled in the art.

3. The '632 Patent

a. *"permits to obtain reduced ph influence in the digestive tract"*

> This term appears in claim 1 of the '632 patent. Claim 1 reads as follows:
>
> A rapidly disintegratable tablet for oral administration and disintegration in the buccal cavity without the use of water, wherein said tablet comprises an active substance and a mixture of non-effervescent excipients and permits to obtain reduced pH influence in the digestive tract and reduced influence of viscosity, said active substance being multiparticulate and in the form of coated microcrystals, or coated microgranules and wherein said mixture of excipients comprises a disintegrating agent and swelling agent which are responsible for the disintegration of the tablet with the saliva present in the mouth, to achieve in less than 60 seconds a suspension easy to swallow.

'632 patent, claim 1. Plaintiffs argue that "permits to obtain reduced ph influence in the digestive tract" as it appears in this claim should be construed to mean "the active ingredient in the tablet is less influenced by stomach pH (*i.e.*, the drug is coated)". D.I. 94 at Revised Ex. A at 8. Defendants contend that the claim limitation is indefinite and does not require construction.

"[A] claim is indefinite only if the 'claim is insolubly ambiguous, and no narrowing construction can properly be adopted.' " *Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d

1332, 1338-39 (Fed. Cir. 2003) (quoting *Exxon Research & Eng'g Co. v. United States*, 265 F.3d 1371, 1375 (Fed. Cir. 2001).). "If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." *Exxon*, 265 F.3d at 1375.

The ' 632 patent teaches that one of the invention's features is, among others, "reduced pH influence in the digestive tract":

> the tablet according to the invention has all the advantages of coated particles which permit to obtain especially a taste-masking, a gastroresistance, a delayed release as well as all the advantages of the multiparticulate forms with modified action or non-modified action, i.e. a great exchange surface, the dispersion, less inter- and intra-individual variations, a very reduced gastric emptying influence as well as **reduced pH influence in the digestive tract**, reduced influence of viscosity and consequently of food and of the position of the body, without local toxic manifestation.

'632 patent, col. 3, lines 41-51 (emphasis added). The patent also teaches that one of the advantages of using a coated multiparticulate dosage form is "gastroresistance," or resistance to the acidic environment of the stomach. *See id.; see also id.* at col. 7, lines 9-14 ("it consists of a tablet which combines a high level technology (control release, of gastroresistance, of taste-masking of the active principle) with a high security of use due to its multiparticulate form by way of the coating during the process of manufacture and to the fact that is disintegration occurs in the mouth, …"). However, contrary to the contentions of Plaintiff, nothing in the specification or the testimony of Defendants' expert, who testified that the invention's "formulation design should lead to gastroresistance," definitively correlates gastroresistance to phrase "reduced ph influence in the digestive tract." In fact, the specification would imply otherwise, as "gastroresistance" and "reduced pH influence in the digestive tract" are listed independently in the portion of the specification quoted above.

That being said, the Court is also not persuaded, at least at this juncture, that the term is unable to be construed and, therefore, indefinite. Overall, the parties simply did not adequately justify their respective arguments. For example, in the parties' joint claim construction chart, Plaintiffs cite to the January 5, 2000 Amendment (Ex. 10 to Byrn Decl.) submitted to the PTO in support of their construction of this term. This Amendment, in the relevant part, states as follows:

> By this amendment, claims 1 and 6 have been cancelled, claim one is replaced with new claim 1 … New claim 1 has been drafted in order to meet objections 1 and 2 page 3 of the action by incorporation of positive language. In that respect the language << Free of acids and of any substance which develops high viscosity in contact with water >> is replaced by << permits to obtain reduced pH influence in the digestive tract and reduced influence of viscosity >>.

Byrn Ex. 10 at TAKZ0001270. Nevertheless, although cited by Plaintiffs, neither party addressed the prosecution history as it relates to this disputed term in much more than a conclusory fashion. Consequently, construction of "reduced ph influence in the digestive tract" shall await summary judgment or trial.

b. *"permits to obtain … reduced influence of viscosity"*

This term appears in claim 1 of the '632 patent. Plaintiffs argue that this limitation should be construed to mean "the formulation influences viscosity less than the prior art formulations of record that have excipients increasing viscosity". D.I. 94 at Revised Ex. A at 9. Defendants contend that the claim limitation is indefinite and does not require construction.

The Court finds that the intrinsic evidence, specifically the prosecution history, supports Plaintiffs' proposed construction. During prosecution, the patentee amended Claim 1 of the patent to include this limitation in order to overcome prior-art references, U.S. Patent

4,886,669 and its counterpart EP 273,005 ("the Zyma references"). Byrn Decl. ¶ ¶ 49-50, Exs. 7 and 8. The Zyma references disclose tablets that use excipients to increase viscosity. Here, the patentee included this specific claim language with respect to viscosity in order to distinguish over the prior-art Zyma references:

"The proposed claim differs from the [US Zyma] reference in that it defines tablets which are free of any substance which develops a high viscosity when in contact with water."

"The proposed claim differs from the [EP Zyma] reference in that it defines tablets which are free of any substance which develops a high viscosity when in contact with water."

Byrn Decl. ¶ 51, Ex. 9. The specification uses the phrase "reduced influence of viscosity," '632 patent, col. 3, lines 49-50, so it is logical that the patentee subsequently amended its former viscosity- related claim language to "permits to obtain . . . reduced influence of viscosity." The Court, consequently, shall construe the disputed claim term consistent with Plaintiff's proposed construction.

c. *"said active substance being multiparticulate and in the form of coated microcrystals, or coated microgranules"*

This term appears in claim 1 of the '632 patent. Plaintiffs propose the following construction: "the active substance is multiparticulate, where individual microcrystals or microgranules containing the active ingredient are entirely coated (*i.e.*, not monolithic)". D.I. 94 at Revised Ex. A at 10. Defendants argue that this limitation does not require construction as its meaning is plain. To the extent that the Court may find construction of the phrase necessary, Defendants propose the following construction: "the active substance being multiparticulate and in the form of coated microcrystals, or coated microgranules". *Id.*

The Court discerns no ambiguity in the term and finds that its ordinary and customary meaning would be clear to one skilled in the art. Consequently, the Court agrees with Defendants that no construction of this term is necessary. Rather, the plain meaning of the term as understood by someone of ordinary skill shall apply.

d. *"disintegrating agent"*

This term appears in claim 1 of the '632 patent. *See* claim 1 ("wherein said mixture of excipients comprises a disintegrating agent and swelling agent which are responsible for the disintegration of the tablet with the saliva present in the mouth"). Plaintiffs assert that this claim term means "a substance, or mixture of substances, added to a tablet to facilitate its breakup or disintegration after administration". D.I. 94 at Revised Ex. A at 11. Defendants, on the other hand, propose the following construction: "a substance, which is not a direct compression sugar, sucrose or lactose, that is a causal agent in the breakup or disintegration of the tablet by a function other than dissolution, and which, in accord with its art-recognized definition, breaks the tablet into smaller particles that dissolve more rapidly than in the absence of the disintegrant". *Id.*

The parties first dispute whether a disintegrating agent must be a causal agent in the breakup of the tablet or merely facilitates disintegration. Plaintiff argues that both the disintegration agent and the swelling agent are needed for disintegration and, therefore, the "disintegration agent" merely facilitates, rather than causes, disintegration. Defendants argue that the disintegration agent must be a causal agent in the disintegration of the tablet.

Exactly the same issue and arguments regarding the same patent and claim term were addressed by the court in *Takeda Pharmaceutical Co. Ltd. v. Teva Pharmaceuticals USA, Inc.*, 668 F.Supp.2d 614 (D. Del. 2009):

> The parties do take issue as to whether a disintegrating agent, as contemplated by claim 1, must "cause" disintegration or merely "facilitate" disintegration. The extrinsic references identified by the parties define "disintegrating agent" as a substance that both "facilitates" and "causes" the breakup or disintegration of a tablet. Looking to the specification, the examples identified as disintegrating agents are known in the art as "super-disintegrants," *i.e.*, excipients whose disintegrating characteristics bear a strong causal relationship to the breakup of a tablet. Super-disintegrants are classified as such due to the comparatively low amount of excipient required to achieve the disintegration of a formulation.
>
> Like the specification, the prosecution history is more consistent with a construction requiring an agent that "causes" disintegration. During prosecution, the examiner rejected the claims of the application leading to the '632 patent ("the application") as unpatentable over U.S. Patent No. 5,073,374 granted to McCarty ("McCarty"). McCarty teaches a quickly dissolving tablet comprising a soluble API, a lubricant and "a soluble, directly compressible tablet excipient." The soluble excipient disclosed in McCarty "is typically a sugar, such as sucrose or lactose." Although claim 1 of McCarty describes a buccal tablet where "... disintegration occurs from 0.5 to 5 minutes after administration" (emphasis added), in traversing the rejection, the patentee nevertheless alleged that McCarty "clear[ly] ... does not teach disintegrating agents."

Teva, 668 F.Supp.2d at 621. Judge Robinson concluded that

> [i]n light of the descriptions of "disintegrating agent" given in the specification and the prosecution history, the court concludes that a causal relationship must exist between the disintegrating agent and the act of disintegration. Put another way, excipients that facilitate disintegration, but are not known in the art to cause disintegration as "disintegrating agents," will not fall within this limitation.

Id.

This Court agrees with Judge Robinson's reasoning and conclusion. Based upon intrinsic evidence, a "disintegrating agent" must have a causal effect on the act of disintegration.

The second area of dispute regarding this term involves Defendants' claim that a disintegration agent cannot be a direct compression sugar, sucrose or lactose. Defendants argue that the patentee disavowed these substances in order to distinguish over the McCarty

reference. However, the Court, having reviewed the prosecution history, does not find the "clear and unmistakable disclaimer" that would be required for Defendants' argument to prevail.

Consequently, the Court shall adopt a construction that combines both parties' proposals and construe "disintegrating agent" as "a substance, or mixture of substances, added to a tablet that is a causal agent in its breakup or disintegration after administration."

e. *"swelling agent"*

This term appears in claim 1 of the '632 patent. Plaintiffs offer the following proposed construction: "a substance, or mixture of substances, which, when contacted with liquid, absorbs the liquid and expands in volume". D.I. 94 at Revised Ex. A at 12. Alternatively, Defendants assert that this term should be construed to mean "a non-causal agent in the disintegration or break-up of the table constituting a three-dimensional network of hydrophilic polymer chains that are chemically or physically crossed linked which absorb either aqueous or organic solutions and thereby expand from 10 to 1,000 times their own weight". *Id.*

The Court finds Plaintiffs' proposed construction to be more in accord with the intrinsic evidence and the customary meaning of the term "swelling agent" to persons of ordinary skill in the art. As Plaintiffs point out, the term "swelling agent" was a well-known term of art at the relevant time. *See* Byrn Decl. ¶ 72, Exs. 18-21. The *Teva* court noted that the "ordinary meaning" of swelling agent is "a substance which, when contacted with liquid, absorbs the liquid and expands in volume." *Teva*, 668 F.Supp.2d at 621.[1] Nothing in the specification or claims of the '632 patent indicates that a different definition for swelling

[1] The parties in that case did not dispute this construction.

agent should apply. Consequently, the Court construes "swelling agent" as "a substance, or mixture of substances, which, when contacted with liquid, absorbs the liquid and expands in volume".

f. *"to achieve in less than 60 seconds a suspension easy to swallow"*

This term appears in claim 1 of the '632 patent. Plaintiffs contend that the phrase means "the mean time to achieve a suspension easy to swallow is less than 60 seconds." *Id.* at 13. Defendants argue that the claim limitation does not require construction and should be considered to have its plain meaning. Alternatively, Defendants propose the following construction: "the absolute time to achieve a suspension easy to swallow is precisely less than 60 seconds". *Id.*

The Court discerns no ambiguity in the term and finds that its ordinary and customary meaning would be clear to one skilled in the art. Consequently, the Court agrees with Defendants that no construction of this term is necessary. Rather, the plain meaning of the term as understood by someone of ordinary skill shall apply.

IV. Conclusion

For the reasons set forth above, the disputed claim terms will be construed as indicated. An appropriate Order shall accompany this Opinion.

/s/ Joel A. Pisano
JOEL A. PISANO, U.S.D.J.

Dated: October 5, 2011